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June 14, 2002

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Citizen Petitions Requesting FDA to Regulate Candy-like Products Containing Tobacco as Adulterated Food Products (Docket Nos. 01P-0572 and 02P-0075)

Dear Sir or Madam:

On April 26, 2002, GlaxoSmithKline Consumer Healthcare, LP ("GSK") submitted additional information to the docket in support of its February 15, 2002, citizen petition. Shortly thereafter, on May 1, 2002, Star Scientific, Inc. ("Star") filed its comments urging FDA to deny GSK's petition. While GSK intends to provide FDA with detailed comments responding to Star's various legal and factual arguments opposing this petition, we are submitting this letter on behalf of GSK to update and supplement the information we filed in this docket on April 26, 2002.

To begin, it is clear that Star is well on its way to achieving its objective of making Ariva available in 25,000 retail stores by the end of its second quarter. Star referred to that goal in a March 29, 2002, press release, which was subsequently posted on the company's website.¹ More recently, Star posted another press release (dated May 15, 2002) on its website that, among other things, updated the company's efforts to market Ariva on a national basis. In that release (attached herein as Exhibit A), Mr. Paul Perito, Star's Chairman, President and COO, declares:

As we maintain leadership in the emerging 'When You Can't Smoke'(TM) market, we continue to expand distribution channels for ARIVA(TM) in the United States. The product now is available in approximately 15,000 stores in more than 40 states, and we currently are on target to make it available to consumers in 25,000 retail outlets by the end of the second quarter (emphases added).

Thus, as GSK pointed out in its April 26, 2002, letter, Ariva is quickly becoming available to consumers across the country.

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At the same time, it appears that Ariva is increasingly being advertised for sale over the Internet by independent tobacco distributors (not Star). In this context, GSK notes that Star takes

¹ This press release is attached as Exhibit A to GSK's letter of April 26, 2002.

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issue with a single sentence in GSK's letter of April 26, 2002. Specifically, in its May 1, 2002, comments, Star claims that GSK stated in that letter that "Star has made Ariva available for sale over the Internet." Star then declares that this statement is incorrect because "Star does not sell Ariva over the Internet."² Unfortunately, Star has misunderstood GSK's sentence and attributed a different meaning to it. In relevant part, GSK's letter stated that "Star has made Ariva available for sale over the Internet through at least one website operated by a distributor of tobacco products." In support of that statement, GSK identified the specific website that has marketed Ariva (www.tobaccobarn.com/dxcart_cigarette_html/dxcart_ariva.html). Accordingly, GSK's April 26, 2002, letter does not represent that Star itself sells Ariva over the Internet – rather, it made clear that Ariva is available for sale over the Internet through a website operated by a tobacco retailer. Nevertheless, to the extent that Star or FDA can construe GSK's statement to suggest otherwise, GSK acknowledges that Star does not sell Ariva over the Internet directly to consumers.³

Star, through its counsel, also suggests that GSK's statement is inaccurate because Star does not ask its distributors to make Ariva available for sale over the Internet.⁴ In support of that contention, counsel for Star has provided GSK with a letter that, it says, exemplifies the position that Star routinely takes with respect to the sale of its tobacco products over the Internet.⁵ In this letter, Star declares that it does not offer its product for sale over the Internet because, for among other reasons, "Internet sales are not sufficiently controlled so as to ensure that minors do not have access [to tobacco products] via the Internet." Moreover, Star's letter advises Internet distributors that "[t]o the extent you choose to make cigarettes available over the Internet, you should understand that Star Scientific is in no way endorsing such activity and/or the legality of such practices." Star also notifies website distributors that it does not authorize them to make any claims relating to its products or any statement suggesting that Star endorses the sale of its products over the Internet.

GSK agrees with Star's concerns about the difficulty of controlling Internet sales of tobacco products to minors. Yet, while Star may not itself sell its products over the Internet and it may disclaim responsibility where its distributors do so, that does not mean that Star's tobacco products, including Ariva, are not offered for sale or sold over the Internet. According to the Discount Cigarettes Shopping Guide (www.discount-cigarettes.org) – a website that contains links to other tobacco websites that carry specific brands of cigarettes – Star's cigarette brands (Gsmoke®, Main Street®, Sport®, and Vegas®) are available over the Internet at a number of

² See Star Scientific, Inc. Comments on GSK Citizen Petition For Regulation of Ariva, May 1, 2002, at pg. 14, fn. 14.

³ Star does, however, maintain a website on the Internet where individuals older than 21 can obtain information about the product (www.goariva.com).

⁴ Telephone communication from Mr. Michael Cole, Esq., Bergeson and Campbell, to Alan Bennett and Bruce Manheim, Bennett, Turner & Coleman.

⁵ See Letter from Robert Pokusa, Paul, Hastings, Janofsky & Walker, LLP, to CMB, Inc., February 17, 2001 (Attached as Exhibit B).

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different sites. In addition, Star's new snuff product – Stonewall™ – is advertised for sale over the Internet at the following webpage address: <http://www.cigaretteoutlet.com/snuff.html>. And, as GSK indicated in its letter of April 26, 2002, Ariva has been offered for sale over the Internet at www.tobaccobarn.com/dxcart_cigarette_html/dxcart_ariva.html. While Star may now tout the fact that it has asked this Internet tobacco distributor to cease such sales, there is no question that Ariva could be purchased at this website for some time.⁶

In its May 1, 2002, letter, Star also assures FDA that it “monitors the Internet in an attempt to prevent [other] tobacco distributors from engaging” in sales of Ariva. A simple search of the Internet, however, demonstrates that such monitoring has failed to prevent advertising and sales of Ariva over the Internet. For example, as of the date of this letter, at least five websites offer Ariva for sale: www.usasmokeshop.com/cig_pages/usa_smokeshop_ariva.html; www.smokeshack.com; www.awesomesmokes.safeshopper.com/2/94.htm?277; <http://aldiscountcigarettes.safeshopper.com/9/93.htm?251>; and www.vafco.com (see Exhibit C).⁷ Three of these websites are readily accessible to minors and allow for the purchase of tobacco products with essentially nothing more than a major credit card and a promise from the purchaser that he or she is legally entitled to buy tobacco products. Moreover, two of these sites advertise Ariva as being “Very Similar In Taste To An Altoid Mint.” A third website declares about Ariva: “Get the Nicotine You Crave When You Are in a Situation Where You Cannot Smoke.”

The inadequacy of Star's purported Internet monitoring program, and the dangers of FDA relying on it, are further exemplified by another Star product -- Gumsmoke® Nicotine Gum – which is also currently advertised for sale on the Internet. In July 1998, FDA advised Star that it had a “number of concerns about the proposed marketing of this product from a regulatory and public health perspective.”⁸ The FDA took that position even though, at the time, Star did not propose to include either tobacco or nicotine in this product. Nevertheless, despite the agency's concerns, this chewing gum product is currently being offered for sale at www.smokeshack.com (click on smoking alternatives) with the following claim: “Helps Fight Nicotine Cravings and Helps You Quit!”⁹ Beyond the obvious improprieties raised by that claim,¹⁰ the existence of this

⁶ Ariva was purchased from this website on February 25, 2002.

⁷ Ariva was purchased over the Internet from www.awesomesmokes.com and www.usasmokeshop.com on May 31, 2002. These sites only required submission of a credit card number and a pledge that the purchaser is 18 years or older. The packages were delivered with no requirement that the recipient demonstrate proof of age (i.e., left at door). On June 7, 2002, Ariva was ordered over the telephone from [vafco.com](http://www.vafco.com) (since the product currently cannot be purchased directly through the website). In connection with that purchase, [vafco.com](http://www.vafco.com) did not ask about the purchaser's age and only required a credit card number. The product was delivered via regular U.S. mail. Ariva was also ordered from aldiscountcigarettes.com, but that order was subsequently canceled because Ariva is “currently unavailable.”

⁸ See Letter from Kevin Budich, Compliance Officer, CDER, to Paul Perito, Paul Hastings, July 22, 1998 (attached as Exhibit D).

⁹ Gumsmoke Nicotine Gum was ordered from this website on May 31, 2002, but it has not yet been delivered.

¹⁰ While this product is clearly a food under the FDCA, the accompanying claims of the Internet retailer make it a

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product on this website (juxtaposed, as it is, immediately above an advertisement for Ariva) suggests that Star's Internet monitoring program is either wholly ineffective or the company does not exercise sufficient controls over Internet tobacco distributors to halt distribution of its products through this medium.

In closing, GSK wishes to emphasize that Star's efforts to downplay Internet sales of Ariva do not change the key issue before FDA: Ariva is an adulterated food product that cannot be legally marketed in the United States until Star submits a food additive petition demonstrating the safety of using tobacco as an ingredient in this candy-like product. Indeed, if anything, the fact that Ariva has been and is available for sale over the Internet -- despite Star's purportedly best efforts to prevent distribution of its product in this manner -- makes it all the more evident that FDA must take regulatory action to address the risks presented by Ariva and other candy-like products containing tobacco. Of course, this is especially true since, as Star itself acknowledges, children have an easier time gaining access to this product over the Internet than in retail stores. To redress this problem, GSK urges FDA to act on its petition by taking action against Ariva and any other candy-like products containing tobacco that could soon reach the market.

Thank you for your consideration of these comments. GSK will soon file more extensive comments addressing the remaining issues raised by Star's submission of May 1, 2002.

Sincerely,



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drug product for the purposes of the statute.